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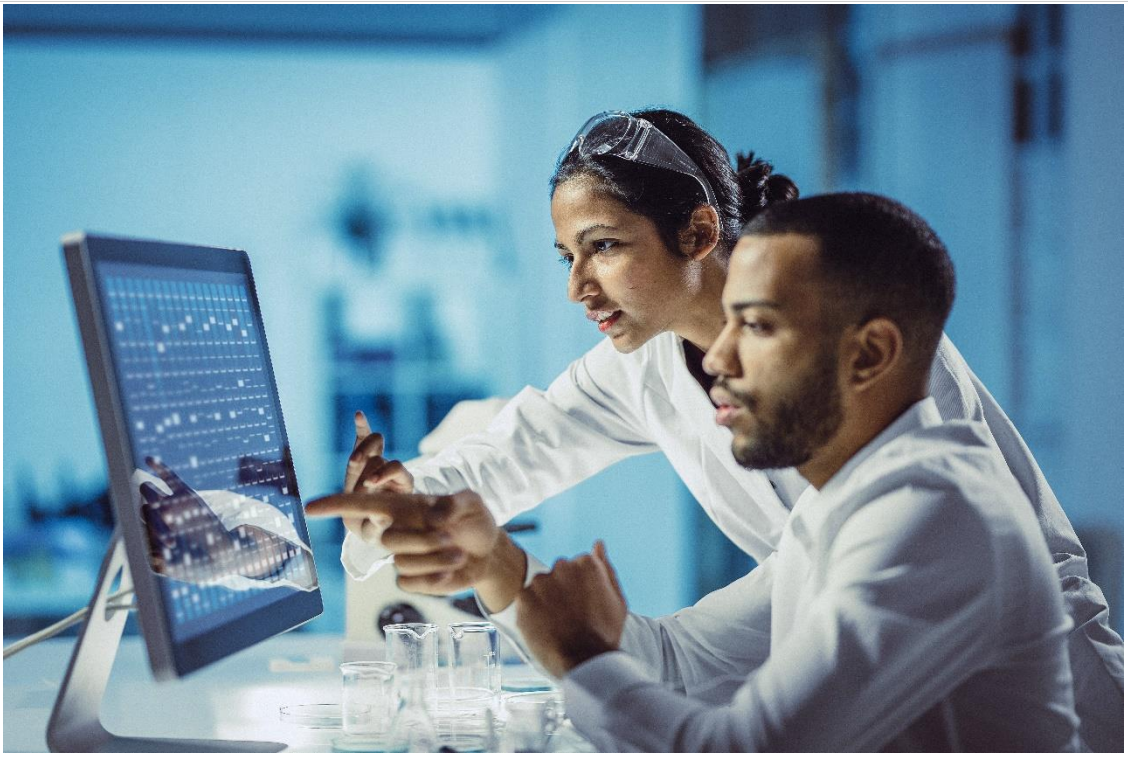
Regulatory review

Your monthly medical devices update

January 2024

Featured in this Newsletter

First batch of EU reference laboratories (EURLs) now designated



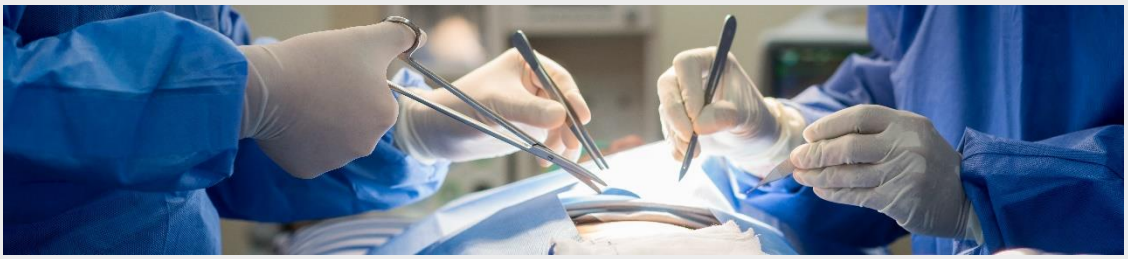
On 5 December 2023, the first batch of EU reference laboratories (EURLs) have been designated through Commission implementing regulation (EU) 2023/2713 and will be required to start their activity from 1 October 2024.

BSI welcomes this announcement as a milestone for increased patient safety and compliance of high-risk IVDs in Europe, and reminds you that the 26 May 2025 deadline for Class D IVDs is approaching. We encourage Class D IVD manufacturers to submit their applications with their Notified Body.

BSI will continue to work towards smooth and timely transitions into EURLs throughout 2024. We are also developing a consistent approach for performance verifications and batch tests on Class D devices.

Learn more

The time for your MDR application is now!



According to Amending Regulation (EU) 2023/607, if you are transitioning your devices to the MDR, you will be able to benefit from extended validity of your directive certificates (until the end of 2027/2028 based on the device classification) for legacy devices if specific conditions are met.

Among these, by 26 May 2024 you must to put into place an MDR compliant QMS and lodge a formal application with a Notified Body for a MDR Conformity Assessment. No later than 26 September 2024, a formal agreement with the Notified Body must be signed.

We strongly recommend that you do not wait until May 2024 to make your MDR application. We encourage you to apply with BSI as soon as possible and well in advance of the above deadlines.

For more guidance visit our MDR dedicated webpage and our FAQs.

BSI unveils reimagined UK website to elevate client experience and global reach

We have recently launched our re-imagined UK website, marking a significant milestone in the introduction of our refreshed brand and commitment to enhance the digital client experience. The new UK website represents a greater integration of our brand positioning with BSI's purpose on core themes and in key sectors, emphasizing our positive impact on society and will be incorporated in other regional websites throughout 2024.

The result of over two years of in depth client and user research, delivered valuable insight used to offer a more relevant and impactful experience users.

Susan Taylor Martin, Chief Executive of BSI, commended the team's efforts, stating, "It's fresh, clean, modern, approachable, and encapsulates the kind of organization we aspire to be." She emphasized the significance of the project in bringing BSI's desired image to you as client.

It includes real life examples of BSI's transformative influence on individuals, organizations and society acting as a platform to share success stories: such as shaping best practices around menstruation and

menopause, accelerating sustainability for the Aston Martin Formula One® Team, and utilizing blockchain to combat illicit medicines and theft in supply chains.

Looking ahead, we plan to continuously enhance the website, incorporating new features and content throughout 2024 and beyond.

Visit now

BSI Compliance Navigator

Compliance Navigator is an online tool developed by BSI that transforms how medical device and IVD device manufacturers manage their EU, UK, MDSAP & FDA regulatory information and standards for greater confidence in their compliance process.

Quick, easy and fully digital, Compliance Navigator enables users to organise product specific compliance documents in one place; alerts them to upcoming changes; notifies them when changes happen; and clearly highlights what's changed and what it means for their business.

Contact us to find more

Events for your calendar

RAPS Euro Convergence 2024

6 - 8 May 2024

RAPS Euro Convergence, the most comprehensive regulatory affairs conference in Europe, focusing on the latest developments in healthcare products in Europe and beyond - medical devices, IVDs, pharmaceuticals, and combination products.

BSI Speakers:

Jayanth Katta - Regulatory Director & Head of Medical Device Notified Body

Suzanne Halliday - VP Regulatory, Regulatory Services

Vishal Thakker - Senior Regulatory Lead & Head of UK Approved Body

Elizabeth Harrison - Global Head, IVD

Alex Laan - Head of IVD Notified Body

Sara Fabi - Regulatory Lead, IVD Notified Body

James Kerr - Technical Specialist & Scheme Manager, IVD Notified Body

Richard Holborow - Head of Clinical Compliance

Rachel Mead - Clinical Regulatory Lead

Sally Humphreys - Clinical Compliance Manager

Aris Tzavaras - Head of AI Notified Body

Daniela Seneca - Regulatory Lead, AI Notified Body

Inma Perez Ruiz - Regulatory Lead, AI Notified Body

Sarah Mathew - Regulatory Lead, AI Notified Body

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